IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

NEOTONUS, INC., Plaintiff v. AMERICAN MEDICAL ASSOCIATION and AMERICAN UROLOGICAL ASSOCIATION, Defendants.	CIVIL CASE NO. 1:04-CV-2050-JTC

O R D E R

This matter is currently before the Court on Defendant American Medical Association and Defendant American Urological Association's motions for summary judgment [#232, #233].

I. Factual Background

A. The parties

Plaintiff Neotonus, Inc. is a privately-held, for-profit corporation based in Marietta, Georgia. Neotonus is in the business of developing technologies for the treatment and management of neuromuscular disorders, including the treatment of female urinary incontinence.

Defendant American Medical Association ("the AMA"), a non-profit corporation based in Chicago, Illinois, is the largest professional association of physicians and medical students in the United States, with approximately

240,000 members. The AMA's physician members practice in all medical specialties and include, among others, urologists, gynecologists, internists, and family practitioners.

Defendant American Urological Association ("the AUA"), a non-profit corporation based in Linthicum, Maryland, is a professional association of physicians practicing urology. The AUA's mission is to foster the highest standards of urological care by providing a wide range of services to its member urologists, including publications, research, annual meetings, continuing medical education, and the formulation of health policy.

B. Neotonus's ExMI technology

In 1998, Neotonus began marketing a medical device referred to as "NeoControl." NeoControl is a chair intended to treat female urinary incontinence, and works using extracorporeal magnetic innervation therapy ("ExMI therapy"). Simply put, ExMI therapy utilizes a pulsed magnetic field to cause the patient's pelvic floor muscles to intermittently contract and relax. The theory behind ExMI is that the contraction/relaxation of the pelvic floor muscles will build strength, endurance, neuromuscular control, and increased circulation in those muscles, thus improving control and continence. The NeoControl device is operated with a pre-programmed smart card that contains a physican's prescription for the parameters of treatment, such as

the frequency, duration, and number of treatments.

C. CPT and the Editorial Panel

Since 1966, the AMA has annually published a work of clinical nomenclature entitled "Current Procedural Terminology" ("CPT"). The purpose of the CPT is to provide a uniform terminology that accurately describes specific medical, surgical, and diagnostic services and procedures to facilitate efficient health care record keeping, information sharing, and efficient processing of claims for payment for services or procedures provided to patients. CPT has been adopted by both public and private health insurance programs (generally, "payors") as the method by which physicians report the services and procedures they provide. CPT is not a reimbursement system, however, and does not constrain a payor's decision to cover or not to cover a particular procedure. Each payor makes its own decisions regarding which services and procedures it will pay for and how much it will pay for each.

There are several different types of CPT codes. Relevant to this case are the Category I code and the Category III code. Category I codes are used to describe a service or procedure that is consistent with contemporary medical practice and performed by many physicians in clinical practice in multiple locations. There are several requirements for a Category I code: (1)

the service or procedure has received the necessary clearance or approval from the Food and Drug Administration; (2) the suggested service or procedure is a distinct service performed by many physicians across the United States; (3) the clinical efficacy of the service or procedure is well-established and documented in U.S. peer-reviewed literature; (4) the suggested service or procedure is neither a fragmentation of an existing code or procedure, or currently reportable by one or more existing codes; and (5) the suggested service or procedure is not requested as a means to report extraordinary circumstances related to the performance of a service or procedure already having a specific CPT code.

Category III codes, on the other hand, are used to describe new and emerging technologies. These codes enable physicians, payors, and health services researchers to evaluate such technologies for clinical efficacy, utilization, and outcomes. Prior to the creation of Category III codes in 2000, services and procedures that did not qualify for a Category I code were identified by physicians using a generic Category I code for "unlisted" procedures.

The CPT Editorial Panel ("Editorial Panel" or "Panel") is a group of experts convened by the AMA that meets regularly to update the CPT code set by creating, deleting, and modifying codes and related descriptors.

Editorial Panel members are not employees of the AMA; they are physicians and other health care professionals who serve on a voluntary basis. Editorial Panel members are nominated by various organizations – primarily, national medical societies and payors – but are subject to the approval of the AMA Board of Trustees. During the relevant time period, the Editorial Panel had 17 members, none of whom was a member of the AUA.

The Editorial Panel is supported by a larger body of advisors, referred to as the CPT Advisory Committee, which is made up of more than 100 volunteer physicians and health care professionals from a broad range of medical specialties. CPT advisors serve the Editorial Panel by, for example, advising the panel members on procedure coding and appropriate nomenclature for a service or procedure. The advisors also provide documentation to the Editorial Panel regarding the medical appropriateness of various procedures and services under consideration for inclusion in the CPT. CPT advisors do not sit on the Editorial Panel, however, and therefore do not vote on applications to create, delete, or modify CPT codes.

D. CPT code application process

In order to request a CPT code for a new procedure or service, the applicant is required to submit an application along with certain specified information, for example, a bibliography or copies of U.S. peer-reviewed

literature supporting the request. When the Editorial Panel staff receives an application for addition, deletion, or modification of a CPT code, it reviews the application to determine whether the Editorial Panel has previously considered the request. If the change requested in the application has been previously considered, the applicant is informed of the Editorial Panel's previous action. If an application raises a new issue, or presents significant new information regarding a previously-addressed coding issue, however, the application is disseminated for comment to those CPT advisors who are likely to be familiar with the service or procedure at issue. The Editorial Panel staff may also communicate with the staff for the various national medical specialty societies represented on the Advisory Committee concerning the status of an advisor's comments, since those comments are incorporated into the materials distributed to Editorial Panel members before the meeting and vote on the application.

At least 30 days in advance of an Editorial Panel meeting, which occur four times a year, the Editorial Panel staff forwards a copy of the completed application to each Panel member, including a summary of the application, a recitation of any comments submitted by CPT advisors, and the scientific literature submitted in support of the application, so that the Panel member may review the often voluminous application and do individual research in

advance of the meeting, if necessary.

At each Editorial Panel meeting, the Panel addresses numerous applications to add, delete, or modify a CPT code. For each application, two of the 17 Editorial Panel members will present the application to the full Panel and make an initial recommendation as to how the Panel should handle the application. After the presentation, the application is open to debate by all Panel members. Applicants are permitted to attend the Editorial Panel meetings, and may be asked questions by the Panel members regarding the procedure or service at issue. After an application is presented and debated, the Editorial Panel votes on the application. A simple majority of votes determines the outcome of the application, which can include: (1) adding, deleting, or modifying a code as requested in the application; (2) postponing or tabling an application pending submission of further information; or (3) rejecting the application. Following the Editorial Panel meeting, an applicant is informed of the result.

A disappointed applicant may submit a written request for reconsideration. The request must contain the reason the applicant believes the Panel's action was incorrect and respond to the Panel's rationale. Once the request is received, it is placed on the agenda for a future meeting of the Editorial Panel Executive Committee.

E. Neotonus's efforts to obtain a Category I code for ExMI

When Neotonus first began marketing the NeoControl device in 1999, it instructed physicians to bill for ExMI therapy using a generic Category I code for unlisted procedures. In March 2000, it decided to seek a specific Category I code for ExMI. Neotonus hired consultants familiar with the CPT application process, and in July 2000, submitted an application for a new Category I code for its technology. In support of its application, Neotonus submitted a number of unpublished abstracts and articles reporting on the theory and physiology of ExMI. Among these materials, only one was an article that had been published in a U.S. peer-reviewed journal. This article, entitled "Extracorporeal Magnetic Innervation Therapy for Stress Urinary Incontinence" (generally, "the Galloway study"), was authored primarily by Dr. Niall Galloway, "Medical Director" of clinical studies involving NeoControl and stockholder at Neotonus. The Galloway study was not a randomized, controlled trial, and was acknowledged by Galloway himself to be "poorly funded" and "poorly monitored." Other persons were similarly suspect of the study. For example, Dr. Rodney Appell of the Cleveland Clinic, a principal investigator of the Galloway study, opined: "I do not think anything was proven by this study. Although there is a publication that will come out concerning this study in general, I think this study was poorly

conceived in that there was no division into subgroups of patients . . . . I would say that the study was totally inconclusive."

Neotonus's initial application did not fare well with the CPT advisors or the Editorial Panel. For example, the advisor representing the American College of Obstetricians and Gynecologists stated that it "d[id] not have enough information to comment." The advisor representing Defendant AUA stated that the AUA's Terminology Committee "reviewed the procedure at its last meeting and determined that there was not enough data to move forward with a code at this time." Dr. Gerald Silverstein, one of the Editorial Panel members tasked with presenting Neotonus's application, commented, based upon his independent review of the materials submitted and research of his own, that the literature submitted by Neotonus was of poor quality and insufficient to support a Category I code.

Following the presentation of the application, the Editorial Panel voted to table the application in order to allow Neotonus to provide "information . . . that substantiates the efficacy and usage of this procedure, including submission of 'peer-reviewed' literature from the United States [and] written support from the primary specialty societies (e.g., American Urological Association)." The Editorial Panel also recommended that the AUA "provide input on whether this procedure should be considered a Category I or

Category III code." The Editorial Panel Executive Committee upheld the tabling of the application.

In September 2001, CPT staff solicited updated comments from members of the Advisory Committee. Comments were received from four advisors, none favorable. For example, the advisor from the American Physical Therapy Association stated that "[t]here is not enough scientific evidence support in the literature and practice environment." Dr. Peter Hollmann, the advisor for the American Geriatric Society, stated that "the supplied literature was not very strong for incontinence or pelvic pain. Long-term efficacy and efficacy vs. placebo not established." The advisor for the AUA also commented that the literature was insufficient to support a Category I code.

After being informed that there was no support for a Category I code, Neotonus informed CPT staff that it wanted to be considered for a Category III code instead. At its November 2001 meeting, the Editorial Panel considered and granted Neotonus's request. Less than two weeks later, however, despite Neotonus's transmission of an e-mail to senior executives and customers lauding the Editorial Panel's decision and stating, "Appropriately, [the] [AMA] has elected to give this Code Category III status as a new medical technology," Neotonus began to inquire about how it could

appeal the assignment of a Category III code and/or request the code be converted into a Category I code. On January 19, 2002, Neotonus submitted additional information for consideration by the Executive Committee, but did not include additional peer-reviewed journal articles reporting on the efficacy of ExMI therapy for female urinary incontinence. The Executive Committee voted to uphold the assignment of a Category III code, stating: "The Executive Committee cited that there has been no CPT specialty support for this procedure, there is limited peer-reviewed United States literature having overlapping authors, and the literature provided does not reflect the efficacy of this technique compared to existing standard treatments . . . ."

In July 2002, Neotonus again submitted an application for a Category I code for ExMI. The new application was distributed to CPT advisors for comment, but received no support from any of the advisors. Consequently, the AMA contacted Neotonus and advised it that Neotonus would be required to get a letter of support from a medical specialty society in order to be placed on the agenda for the next meeting. The AMA further noted that, in order to receive favorable consideration, Neotonus would need to submit U.S. peer-reviewed literature demonstrating the efficacy of ExMI. On December 17, 2002, the AUA, the American College of Obstetricians and Gynecologists, and the American Urogynecolic Society jointly commented that they "continue to

not support Neotonus' [sic] appeal to change the supervised [ExMI] for the treatment of incontinence code from a level III to a level I code. We have reviewed the supplemental information submitted by Neotonus . . . and we believe the scientific evidence supporting the ExMI treatment for incontinence still is not sufficient to support the change from a level III to a level I code based on the scientific evidence submitted for review." Because Neotonus was unable to garner support from any CPT advisor, it was informed that its application would not be considered by the Editorial Panel.

On April 3, 2003, Neotonus contacted the AMA requesting "appeal" of the decision not to convert the Category III code to a Category I code. Neotonus referenced a letter from a group called the Urology Society of America supporting consideration of Neotonus's request. Although this group had no representative on the Advisory Committee and was otherwise unfamiliar to CPT staff, the Editorial Panel Executive Committee agreed to treat its statement of support as a sufficient basis for consideration of Neotonus's application by the Editorial Panel. At its May 2003 meeting, the Editorial Panel considered the application, but denied Neotonus's request to convert its code. The reasons cited by the Panel were primarily the lack of reliable studies or U.S. peer-reviewed literature indicating the efficacy of ExMI therapy. Neotonus was informed that a new application would not be

considered until additional information was provided to create a reason for reconsideration of the coding decision.

Following the rejection of Neotonus's application, the AUA informed CPT staff that it was establishing an expert panel to review the ExMI technology to provide a separate inquiry into the efficacy of the treatment. The Editorial Panel decided that, when the results of the AUA study were in, they would be treated as "new information" sufficient to provide a basis for reconsideration of Neotonus's application for a Category I code. On September 30, 2003, the AUA expert panel reported the results of its work:

> [W]hereas ExMI does offer some short-term benefit for patients who are actively receiving ExMI therapy, there is a lack of durability of this therapy after conclusion of the proposed therapeutic course (sixteen weekly treatments). The reviewed literature indicated some variability in the overall length of retained benefit once the treatment course has been stopped, however, it would appear that most patients revert to baseline symptoms over a period of time ranging from a few weeks to a few months post therapy. Therefore there is no apparent retained long-term durability that benefits the patient. [Thus] the [CPT] classification in our view should remain unchanged.

Dr. Robert Dmochowski, the chair of the expert panel (and a physician who had used the NeoControl device), explained that the expert panel's basic conclusion was that ExMI therapy is not effective for the treatment of female urinary incontinence.

Based on this information, as well as new concerns that "the treatment

is administered with no physician interaction with the patient," the Editorial Panel denied the application. This lawsuit followed. Other facts, as relevant to consideration of Defendants' motions, will be discussed below.

II. Legal Standard

Summary judgment is appropriate when no genuine issues of material fact are present and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56. The movant carries the initial burden and must show the Court that there is "an absence of evidence to support the nonmoving party's case." Celotex Corp. v. Catrett, 477 U .S. 317, 325, 106 S. Ct. 2548, 2554 (1986). "Only when that burden has been met does the burden shift to the nonmoving party to demonstrate that there is indeed a material issue of fact that precludes summary judgment." Clark v. Coats & Clark, Inc., 929 F.2d 604, 608 (11th Cir. 1991). The nonmovant is then required "to go beyond the pleadings" and to present competent evidence in the form of affidavits, depositions, admissions and the like, designating "'specific facts showing that there is a genuine issue for trial.'" Celotex, 477 U.S. at 324, 106 S. Ct . at 2553 (quoting Fed. R. Civ. P. 56(e)). "The mere existence of a scintilla of evidence" supporting the nonmovant's case is insufficient to defeat a motion for summary judgment. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 252, 106 S. Ct. 2505, 2512 (1986). Resolving all doubts in favor of the nonmoving

party, the Court must determine "whether a fair-minded jury could return a verdict for the plaintiff on the evidence presented." Id.

III. Discussion

In its Complaint, Neotonus charge Defendants AMA and AUA with violations of §§ 1 and 2 of the Sherman Act and common law conspiracy to restrain trade. Neotonus also charges Defendant AUA with tortious interference under Georgia law. The Court discusses each of Neotonus's claims in turn.

A. Section 1 of the Sherman Act

Count I of Neotonus's Complaint charges that the AMA and AUA "have engaged in an unlawful combination and conspiracy unreasonably to restrain . . . interstate commerce in the treatment of female urinary incontinence" in violation of § 1 of the Sherman Act. Section 1 of the Sherman Act prohibits contracts, combinations, and conspiracies in restraint of trade. 15 U.S.C. § 1 ("Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal.").

An "agreement"[1] between two or more persons is an essential element

[1] The words "contract," "combination," and "conspiracy" in the text of § 1 are interchangeable terms used "to describe the requisite agreement between two or more persons to restrain trade." Todorov, 921 F.2d at 1455 (emphasis added).

of a § 1 claim. Todorov v. DCH Healthcare Auth., 921 F.2d 1438, 1455 (11th Cir. 1991); Aquatherm Indus., Inc. v. Fla. Power & Light Co., 145 F.3d 1258, 1262 (11th Cir. 1998) ("It is fundamental that a plaintiff establish an agreement between two or more persons to restrain trade; unilateral conduct is not prohibited by § 1."). To prove the requisite agreement, Neotonus "must demonstrate 'a unity of purpose or a common design and understanding, or a meeting of the minds in an unlawful arrangement.'" Todorov, 921 F.2d at 1455-56 (citation omitted). A party asserting violation of § 1 will rarely be able to show an explicit agreement to restrain trade; thus, it must often resort to "inferences drawn from the behavior of the alleged conspirators." Id. at 1456. When a party attempts to show an unlawful agreement based on circumstantial evidence, however, the range of permissible inferences is limited. Id. Thus, in order to survive summary judgment, Neotonus must "present evidence that reasonably 'tends to exclude the possibility' that the alleged conspirators acted independently." Id. (citation omitted). Thus, for example, "conduct as consistent with permissible [activity] as with illegal conspiracy does not, standing alone, support an inference of antitrust conspiracy." Id. (quoting Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 588, 106 S. Ct. 1348, 1356 (1986)).

The thrust of Neotonus's claim under § 1 is that the AMA and AUA

conspired to deny its various applications for a Category I code. Because no reasonable jury could conclude that the AMA and AUA agreed to deny the applications – much less unlawfully agreed to do so – Neotonus's claim under § 1 fails. The record reveals that each member of the CPT Editorial Panel made a decision on Neotonus's applications based not on some agreement with the AUA, but on each member's personal analysis of the information submitted in support of the application, personal research, and the opinions expressed by various medical specialty societies that commented on the applications. For example, Editorial Panel member Dr. Karen Borman explained:

> While I considered the opinions of the advisors, I made up my own mind based on the proposal and evidence submitted [by Neotonus]. It is my practice to make a conscientious effort to review all of the material and to come to an independent decision regarding CPT proposals. After listening to all of the discussions, reading the literature, the proposal, and the advisor opinions, I made an independent judgment that there was not convincing evidence that ExMI was a service that deserved a Category I code.

Another Panel member, Dr. Glenn Littenberg, explained:

> Although I thought the [ExMI] technology seemed unique and interesting, the medical literature offered in support of the device was very weak . . . . The quality of the studies was poor, with research designs that were subject to bias and unreliable results. For a medical condition of such high frequency, the number of patients treated and the randomization, blinding, observations, and particularly follow-up of patients was deficient. . . . For the reasons described above, I reached my own independent

> judgment that Neotonus' [sic] device did not satisfy the requirements of a Category I code.

Each of the other Panel members, through deposition or affidavit testimony, gave similar explanations for their decisions on Neotonus's applications.

Neotonus makes several arguments in an attempt to overcome the overwhelming evidence that the CPT Editorial Panel independently determined that the ExMI technology was unworthy of a Category I code. Primarily, it argues the Editorial Panel members merely deferred to the AUA's opinion that the ExMI therapy was unworthy of a Category I code and adopted its position. This argument is without merit. First, it is contradicted by the unrefuted evidence that each of the Editorial Panel members acted independently and without influence from the AUA in voting on Neotonus's applications. Second, contrary to what Neotonus appears to believe, it is not inappropriate for the Editorial Panel, when tasked with reviewing an application for some type of medical therapy, to seek the advice of the respective medical specialty societies most knowledgeable or experienced in the relevant field. Seeking the advice of the relevant medical specialty society and abdicating the code setting process are not equivalent. Neotonus has presented no persuasive evidence that this situation is materially different from the one faced by the Eleventh Circuit in Todorov, where a hospital refused to grant radiology privileges to the plaintiff based, in part,

upon a recommendation it received from the staff radiologists. The court's observation is germane here: "[Neotonus's] complaint is simply that the [AUA], in this case, acted consistently with the recommendations it received. The Supreme Court has faced this type of procedure before in antitrust cases involving different areas. In these cases, the Court has also refused to infer a conspiracy from this bare circumstantial evidence." Todorov, 921 F.2d at 1458. The mere consistency between the AMA's and AUA's opinion on the efficacy of Neotonus's product does not, standing alone, give rise to an inference of conspiracy. See id. at 1456 ("[C]onduct as consistent with permissible [activity] as with illegal conspiracy does not, standing alone, support an inference of antitrust conspiracy.") (quoting Matsushita, 475 U.S. at 588, 106 S. Ct. at 1356).

Neotonus next argues that the AUA somehow dominated the Panel. This contention is also without merit. Despite what Neotonus previously represented to the Court, it is now undisputed that no member of the AUA sat on the Editorial Panel at any time during which Neotonus's applications were considered. While there was one representative of AUA among the Editorial Panel's approximately 120 CPT advisors, Neotonus has failed to present any evidence that any member of the Editorial Panel, much less enough members to influence the vote, came to an agreement with this

person.

Finally, Neotonus attempts to create an issue of fact for trial by offering its expert's opinion that "Neotonus met the criteria for a CPT I code by 2002, and certainly no later than 2003." This assertion, even if true, is insufficient to create an issue of fact for trial because it does little to call into question the virtually universal criticism that the efficacy of the ExMI therapy was not well-established. The above discussion makes clear that the AMA's various denials of Neotonus's applications was unilateral. Thus, the agreement required for a § 1 claim is absent.[2]

Assuming arguendo that Neotonus could show a conspiracy, or at least create an inference of conspiracy sufficient to survive summary judgment, it must also show that the agreement was "designed to achieve an unlawful objective." Aquatherm, 145 F.3d at 1262; cf. Todorov, 921 F.2d at 1455 ("Liability will only attach to agreements designed unreasonably to restrain trade in, or affecting, interstate commerce.") (emphasis omitted). In this case, even if Neotonus could show the AMA and AUA agreed to deny its applications for a Category I code, it still could not prevail on its § 1 claim because it cannot show that the objective of the agreement – to deny the

[2] Because the AMA unilaterally denied Neotonus's application for a Category I code, the AUA is not liable under § 1: the AUA was not responsible for the decision, and consequently, the injury of which Neotonus complains. Todorov, 921 F.2d at 1459 ("[F]ail[ure] to show causation is fatal to a section 1 claim.")

applications – was unreasonable or unlawful.

Virtually every person and organization given the opportunity to comment on the ExMI technology reached the same conclusion as the Editorial Panel – that it was not worthy of a Category I code. For example, almost every national medical specialty society and group practice association that commented on Neotonus's various applications concluded that Neotonus had not met the requirements for a Category I code. For example, the CPT advisor from the American Physical Therapy Association commented that "[t]here is not enough scientific evidence support in the literature and practice environment." Dr. Susan Turney, the CPT advisor for the American Group Practice Association, stated that "despite the purported large numbers of treated patients, there is a startlingly brief amount of literature to attest to the efficacy of treatment, and no randomized studies."

In another instance, the American College of Obstetricians and Gynecologists commented that it "is unable to support the CPT proposal submitted on behalf of Neotonus, Inc. . . . After reviewing the data, our committee members concluded that while there is some evidence for effectiveness, there are no randomized clinical trials supporting this therapy. Their view is that there is inadequate long-term data, and felt it would be premature to support a change to a Category I code at this time." Numerous

other medical specialty societies indicated a lack of support for the Category I code application. In fact, Neotonus has failed to point to one specialty society represented on the AMA's House of Delegates that supported its application for a Category I code.

The record also reveals that payors have independently, and almost uniformly, concluded that the current scientific literature does not bear out the efficacy of ExMI therapy. For example, Regence Blue Cross/Blue Shield of Oregon concluded in 2003 that "the scientific evidence was insufficient to support any conclusions concerning the effectiveness of the Neotonus magnetic stimulation device." As late as February 2006, Cigna had concluded that

> A review of the published peer review evidence-based literature reveals limited data that supports the efficacy of [ExMI]. Limitations of the studies include small patient populations, lack of a control group, lack of long-term results, and inconsistencies in the types of devices and procedural protocols. The studies do not demonstrate that outcomes from [ExMI] are equal to or superior to those attained with proven treatment methods. Although [ExMI] may produce some initial short-term improvement of incontinence, its long-term effect remains unknown. Review of the available scientific literature does not support the efficacy of [ExMI] stimulation in the treatment of urinary incontinence.

Finally, five independent technology assessments concluded that ExMI therapy has not been proven to be effective. For example, the ECRI Health Technology Assessment Information Service concluded "the published data do

not support the use of magnetic muscle stimulation for urinary incontinence" and "no evidence-based conclusions may be drawn regarding the effectiveness of magnetic muscle stimulation on urinary incontinence." In addition, as late as October 2004 the California Technology Assessment Forum, an affiliate of Blue Cross/Blue Shield of California, published a technology assessment of ExMI therapy which concluded that "the literature concerning ExMI was insufficient to permit conclusions about (a) the effect of the technology on health outcomes, (b) the benefit as compared to established treatment alternatives, and (c) whether the proffered benefits were attainable outside of the investigational setting."

Finally, it is noteworthy that Neotonus has yet to provide a rational explanation for why the AMA would act against its own self-interest in denying Neotonus's various applications for a Category I code. Neotonus claims that ExMI therapy is relevant not only to urologists, but also to gynecologists, family practitioners, and physical therapists. The AMA's membership includes practitioners from all of these specialties. Thus, Neotonus's contention, if believed, would compel the conclusion that the AMA, through the Editorial Panel, deprived its more numerous member gynecologists, internists, and family practitioners from the use of an effective device simply for the benefit of its less numerous member urologists. This

lack of explanation for the AMA's conduct only bolsters the conclusion that no violation of the antitrust laws is present. Similar to the observation in Todorov, "[Neotonus] does not explain why the [AMA] would want to act this way; [it] simply concludes that it did." Todorov, 921 F.2d at 1457; see also Matsushita, 475 U.S. at 587, 106 S. Ct. at 1356. ("[I]f the factual context renders [the plaintiff's] claim implausible – if the claim is one that simply makes no economic sense – [the plaintiff] must come forward with more persuasive evidence to support their claim than would otherwise be necessary.").

No reasonable jury could conclude the AMA and AUA violated § 1 of the Sherman Act. Thus, Defendants' motion for summary judgment on that claim is **GRANTED**.

B. Section 2 of the Sherman Act

Count I of Neotonus's Complaint also charges that the AMA and AUA "have engaged in an unlawful combination and conspiracy unreasonably to monopolize . . . interstate commerce in the treatment of female urinary incontinence" in violation of § 2 of the Sherman Act. The Court has already concluded the AMA acted unilaterally in denying Neotonus's applications; thus, no conspiracy or agreement is present and this portion of Count I fails. Count II, on which the Court focuses here, charges that Defendant AUA

monopolized and/or attempted to monopolize the market for the treatment of female urinary incontinence in violation of § 2 by, among other things, improperly influencing the Editorial Panel to reject Neotonus's applications for a Category I code and influencing medical treatment payors to refuse to reimburse for ExMI therapy.

Section 2 of the Sherman Act prohibits monopolization, attempted monopolization, and conspiracy to monopolize. 15 U.S.C. § 2 ("Every person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations, shall be deemed guilty of a felony . . . ."). Section 2 reaches unilateral, as well as concerted, conduct. Todorov, 921 F.2d at 1459.

The first step in determining whether a defendant has violated § 2 involves identification of the relevant market and a determination of whether the defendant possesses monopoly power in that market. Morris Commc'ns. Corp. v. PGA Tour, Inc., 364 F.3d 1288, 1295 (11th Cir. 2004); Tech. Res. Servs., Inc. v. Dornier Med. Sys., Inc., 134 F.3d 1458, 1466 (11th Cir. 1998). With respect to the first question, the Court accepts as correct Neotonus's allegation that the relevant market is "the market for the treatment of female urinary incontinence in the United States." The question thus becomes

whether the AUA possesses monopoly power in that market.

Urologists are only one among the many types of physicians (and other practitioners) who practice in the market for the treatment of female urinary incontinence. In fact, urologists comprise only 7% of the this market; the remainder is occupied by obstetricians, gynecologists, family practitioners, and internists. Moreover, there are at least eleven types of competing treatments for urinary incontinence, which range from least invasive (e.g., Kegel exercises) to most invasive (e.g., surgery). Confronted with this information, which demonstrates that the AUA clearly does not have monopoly power by virtue of its market share, Neotonus argues that the AUA possesses monopoly power by virtue of its "de facto standard-setting authority" and consequent ability to influence the AMA to exclude Neotonus from competition. See PGA Tour, 364 F.3d at 1294 (defining monopoly power as "the power to control prices in or to exclude competition from the relevant market"). Because the AMA acted unilaterally in denying the applications for a Category I code, Neotonus's hypothesis that the AUA has monopoly power by virtue of "de facto standard-setting authority" necessarily fails.

Nevertheless, assuming arguendo that the AUA has monopoly power, Neotonus would still be unable to make out a violation of § 2. Primarily, Neotonus has failed to show that the AUA engaged in predatory or

anticompetitive conduct. See PGA Tour, 364 F.3d at 1294. The AUA's position on the ExMI therapy and Neotonus's applications was consistent with virtually every organization that had an opportunity to comment on the technology. The Court fails to understand how the AUA's expression on the effectiveness of Neotonus's technology – particularly when consistent with almost every other organization's opinion – was either predatory or anticompetitive. Neotonus attempts to show predatory conduct "by showing that there was no legitimate purpose to denying a CPT I code." Again, however, as shown by the plethora of individuals and organizations who commented on the ExMI technology, the AUA's expression of lack of effectiveness, in view of the paucity of peer-reviewed literature and scientific data, was not anticompetitive or predatory.

In addition, Neotonus has failed to show causation. Neotonus concedes that all of the damages it has suffered in this case result from the denial of a Category I CPT code. It was the AMA, not the AUA, that was responsible for the denial of Neotonus's applications. Thus, the AUA cannot be liable for any damages Neotonus has suffered as a result of the denials. See Todorov, 921 F.2d at 1462 ("Since the decision to deny Dr. Todorov's application for privileges was a unilateral act by [the hospital], Dr. Todorov is unable to prove that the radiologists caused his injury. Thus, he cannot maintain an

action against the radiologists under section 2 . . . .").[3]

Finally, Neotonus's claim under § 2 fails because the AUA's actions were, in view of the lack of scientific literature to bolster Neotonus's claims of efficacy, perfectly legitimate business actions in the context of a medical specialty society and an advisor to the AMA. Cf. Tech. Res. Servs., Inc. v. Dornier Med. Sys., Inc., 134 F.3d 1458, 1466 (11th Cir. 1998) ("A defendant can escape § 2 liability if the defendant's actions can be explained by legitimate business justifications."); PGA Tour, 364 F.3d at 1295.

No reasonable jury could conclude the AUA violated § 2 of the Sherman Act. Thus, Defendant AUA's motion for summary judgment on that claim is **GRANTED**.

C. State law claims

In Count III, Neotonus alleges that the AUA tortiously interfered with business relations in violation of Georgia law. To establish entitlement to relief, Neotonus must show: "(1) improper action or wrongful conduct by the defendant without privilege; (2) the defendant acted purposely and with malice with the intent to injure; (3) the defendant induced a breach of contractual obligations or caused a party or third parties to discontinue or fail

[3] Moreover, to the extent Neotonus would attempt to claim damages from a lack of coverage of the ExMI therapy, it is clear that the AUA was not responsible. Every payor deposed in this case testified that its coverage decision resulted from its own independent assessment of the clinical literature relating to ExMI's efficacy.

to enter into an anticipated business relationship with the plaintiff; and (4) the defendant's tortious conduct proximately caused damage to the plaintiff." Tidikis v. Network for Med. Commc'ns. & Research LLC, 619 S.E.2d 481, 486 (Ga. Ct. App. 2005). This claim fails for the reasons discussed above, primarily, because Neotonus has failed to show wrongful conduct or causation.

In Count IV, Neotonus charges the AMA and AUA with common law conspiracy to restrain trade in violation of Georgia law. This claim fails for the reasons discussed in Section III.A. with respect to § 1 of the Sherman Act.

IV. Conclusion

At bottom, this lawsuit appears to be an attempt on the part of Neotonus to have a federal court second-guess the medical expertise and opinions of 17 Editorial Panel members and numerous medical speciality societies and payors that determined Neotonus's ExMI therapy is not worthy of a Category I code. Because no reasonable jury could conclude that Defendants AMA and AUA ran afoul of the federal antitrust laws or Georgia law related to tortious interference or common law conspiracy to restrain

trade, Defendants' motions for summary judgment [#232, #233] are **GRANTED**.

SO ORDERED, this 3rd day of August, 2007.

JACK T. CAMP
UNITED STATES DISTRICT JUDGE